CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MERCK & CO., INC.

I. PREAMBLE

Merck & Co., Inc., on behalf of itself and its subsidiaries to the extent they are doing business in the United States, including its principal operating subsidiary, Merck Sharpe & Dohme Corporation (collectively "Merck"), hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Contemporaneously with this CIA, Merck is entering into a Settlement Agreement with the United States. Merck will also enter into settlement agreements with various States (State Settlement Agreement) and Merck's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), Merck established a voluntary compliance program applicable to all Merck employees (Compliance Program). Merck's Compliance Program includes a Vice-President, U.S. Business Practices and Compliance/Global Support (who is the Compliance Officer for Global Human Health – U.S. Markets (GHH-U.S.), Merck Vaccines (MV) and the Global Commercial Support Organizations (GCSO)) (referred to as the "Compliance Officer"). Merck also established the U.S. Business Practices and Compliance/Global Support group (BP&C) that works in conjunction with the head of Merck's Office of Ethics (Ethics Officer). The Compliance Program also includes a Code of Conduct, written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and appropriate

disciplinary procedures, screening measures for Ineligible Persons, and regular internal auditing procedures.

In 2010, Merck entered a Unified CIA with the OIG. As set forth in more detail below in Section II, this CIA shall supersede and replace the Unified CIA.

Merck shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Merck may modify its Compliance Program as appropriate, but, at a minimum, Merck shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. Merck's obligations under the Unified CIA shall continue through the Effective Date of this CIA at which point Merck's obligations under the Unified CIA shall be superseded by the terms of this CIA. The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). The period of the compliance obligations assumed by Merck under this CIA shall be 5 years from the Effective Date of this CIA, unless otherwise specified. The first reporting period shall be from the Effective Date to December 31, 2012. Thereafter, each one-year period shall be referred to as a "Reporting Period." The last Reporting Period shall start on January 1, 2016, and shall end five years after the Effective Date.

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Merck's final Annual Report; or (2) any additional materials submitted by Merck pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

   a. all owners of Merck who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading) and all directors of Merck.;

b. all employees of Merck and Merck & Co., Inc. who are engaged in or have responsibilities relating to any of the Covered Functions (as defined below in Section II.C.8); and

c. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions in the United States on behalf of Merck.

Notwithstanding the above, the term Covered Persons does not include: (1) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year; (2) employees, contractors, subcontractors, agents or other personnel of Merck Manufacturing Division (MMD), Merck Animal Health, or Merck Consumer Products Divisions so long as they do not have responsibilities relating to any of the Covered Functions; and (3) to the extent not covered under other provisions of the CIA, employees, contractors, subcontractors, agents or other personnel of Merck Research Laboratories (MRL) so long as they do not have responsibilities relating to any of the Covered Functions.

2. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to any of the Covered Functions.

3. "Government Reimbursed Products" refers to all Merck pharmaceutical products (including vaccines) promoted or sold by Merck in the United States or pursuant to contracts with the United States that are reimbursed by Federal health care programs;

4. The term "Promotional Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable review committees.

5. The term "Product Related Functions" includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal health care program and/or FDA requirements and distributed to healthcare professionals (HCPs) and healthcare institutions (HCIs) about Government Reimbursed Products including those functions relating to any applicable review committees and to Merck's Global Medical Information and Operations Department (GMIO); (b) contracting with HCPs licensed in the United States to conduct post-marketing clinical trials and other post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as Drugdex or other compendia of information about Government Reimbursed Products) used in connection with the determination of coverage by a Federal health care program for the product (Compendia).

6. The term "Government Pricing and Contracting Functions" refers to the collection, calculation, verification, or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8), the Medicare Program (42 U.S.C. §§ 1395-1395hhh), and other government programs (including the 340B Drug Pricing Program, codified at 42 U.S.C. § 256b (the 340B Program)). Persons engaged in these functions include individuals whose job responsibilities include the calculation and reporting of Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price, the 340B Program ceiling price, Average Wholesale Price (AWP) (if applicable), and all other information calculated and reported by Merck and used in connection with Federal health care programs.

7. The term "Government Payor Related Functions" refers to Promotional Functions and Product Related Functions as they relate to interactions between Merck and state Medicaid payors, pharmacy benefit managers (PBMs), or other individuals or entities under contract with or acting on behalf of State Medicaid payors.

8. The term "Covered Functions" refers to "Promotional Functions," "Product Related Functions," "Government Pricing and Contracting Functions," and "Government Payor Related Functions" collectively.

9. The term "Third Party Personnel" shall mean employees of entities with whom Merck has or may during the term of the CIA enter into agreements to promote or co-promote a Government Reimbursed Product or to engage in joint promotional activities relating to a Government Reimbursed Product. Merck represents that: 1) the Third Party Personnel are employed by independent entities other than Merck; 2) Merck does not control Third Party Personnel; and 3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Merck agrees to promote compliance by Third Party Personnel with Federal health care program requirements and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.4 related to Third Party Personnel. Provided that Merck complies with the requirements of Sections III.B.2, and V.B.4, Merck shall not be required to fulfill the remaining CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

10. The term "Third Party Educational Activity" shall mean any scientific, educational, or professional program, meeting, or event conducted by a Third Party and supported by Merck, including but not limited to continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

11. The term "Acknowledge" as used in this CIA means a written or electronic verification that the signatory agrees with the statements set forth in the verification.

III. CORPORATE INTEGRITY OBLIGATIONS

Merck shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Responsibilities of Certain Merck Employees and the Board of Directors.

1. *Generally*. Prior to the Effective Date, Merck established a comprehensive Compliance Program. The Compliance Program now includes: the Compliance Officer, a Compliance Committee, and BP&C, which works in conjunction with the Ethics Officer.

Among other things, BP&C has responsibility for the design, development, and implementation of compliance practices and processes guiding sales and marketing activities for GHH-U.S., MV, and GCSO. The President of GHH-U.S. (the President) and the Compliance Officer co-chair the Compliance Committee (the "Compliance Committee").

2. *Compliance Officer*. Prior to the Effective Date, Merck appointed an individual to serve as its Compliance Officer (as defined in Section I above) and Merck shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer is and shall continue to be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Compliance Officer shall be a member of senior management of GHH-U.S., shall report directly to Merck's Executive Vice President/Chief Ethics and Compliance Officer who heads the Global Compliance Organization and who reports directly to the Chief Executive Officer of Merck, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Merck or an authorized subcommittee thereof (Board), and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Merck as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Merck shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after the change.

3. *Compliance Committee*. Prior to the Effective Date, Merck appointed a Compliance Committee which, in conjunction with the Compliance Officer, has primary

responsibility for promoting compliance within GHH-U.S., MV, and GCSO. Merck shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer, the President of GHH-U.S., and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as legal, medical, marketing, sales, human resources, finance, research and development, and operations). The Compliance Officer and the President of GHH-U.S. shall co-chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Merck's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Merck shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Board Compliance Obligations*. The Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board shall, at a minimum, be responsible for the following:

a. The Board shall meet at least quarterly to review and oversee Merck's Compliance Program, including but not limited to the performance of the Compliance Officer. The Board shall receive updates about the activities of the Compliance Officer and other compliance personnel, including updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements, and shall evaluate the effectiveness of the Compliance Program.

b. For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of Merck's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors (or an authorized subcommittee thereof) has made a reasonable inquiry into the operations of Merck's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the performance and activities of the Compliance Officer for the time period **[insert time period]**. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Merck has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Merck.

Merck shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

5. *Management Accountability and Certifications*: In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Merck officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Merck business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the President of GHH-U.S.; Vice President, Primary Care; Vice President, Specialty and Hospital Commercial Operations; Senior Vice President, Managed Markets and Policy; Vice President, Marketing and Customer Solutions; Vice President, Strategy, Development and Innovation; Senior Vice President, Global Pharmaceuticals Franchises and Global Market Access; President, Merck Vaccines; Senior Vice President, Global Medical Affairs; Senior Vice President, GHH Finance; Vice President, Finance, U.S. Market; Chief Medical Officer; the President of MRL and, to the extent that a Merck business unit performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other appropriate Merck executives, vice-presidents, or leaders or heads of business units as would be necessary to ensure that there is a certifying officer or employee covering each such business unit.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Merck policies, and I have taken steps to promote such compliance. In the event that I have identified potential issues of noncompliance with Federal health care program requirements, FDA requirements and/or obligations of the Corporate Integrity Agreement, I have referred all such issues consistent with Merck's processes for reporting potential misconduct for further review and follow-up. Apart from those referred issues, I am not currently aware in _____ [insert department name] of any violations of applicable Federal healthcare program requirements, FDA requirements, or Corporate Integrity Agreement requirements. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct*. Prior to the Effective Date, Merck established both a general corporate Code of Conduct and a set of Ethical Operating Standards. Merck's Ethical Operating Standards provide guidance relating to the Covered Functions, including the promotion, marketing, and sale of Government Reimbursed Products in the United States. Merck has made (or, within 90 days after the Effective Date, shall make) the Ethical Operating Standards available to all Covered Persons. Merck makes, and shall continue to make, adherence to these Ethical Operating Standards an element in evaluating the performance of all employees who are Covered Persons. The Ethical Operating Standards include, or within 90 days after the Effective Date, shall be revised to address or include the following:

a. Merck's commitment to full compliance with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to the Covered Functions;

b. Merck's requirement that all of its Covered Persons shall be expected to comply with all applicable legal requirements, with all Federal health care program requirements, FDA requirements, and with Merck's own Policies and Guidance Documents (defined below in Section III.B.3), including but not limited to, the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);

c. Merck's requirement that Covered Persons are responsible for adhering to the Policies and Guidance Documents and are expected to report suspected violations of any Federal health care program requirements, FDA requirements, or of Merck's own Ethical Operating Standards and Policies and Guidance Documents;

d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and Merck's Ethical Operating Standards and Policies and Guidance Documents;

e. the possible consequences to both Merck and Covered Persons of failure to comply with Federal health care program requirements, FDA requirements, and/or with Merck's own Ethical Operating Standards or Policies and Guidance Documents, or the failure to report such noncompliance; and

f. the right of all individuals to use the Disclosure Program described in Section III.E, and Merck's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished within 180 days prior to the Effective Date, within 90 days after the Effective Date, each Covered Person shall Acknowledge in writing or in electronic form that he or she has received, read, understood, and shall abide by Merck's Ethical Operating Standards. New Covered Persons shall receive the Ethical Operating Standards and shall complete the required Acknowledgement within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Merck shall periodically review the Ethical Operating Standards to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Ethical Operating Standards shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall Acknowledge, in writing or in electronic form, that he or she has received, read, understood, and shall abide by the revised Ethical Operating Standards within 30 days after the distribution of the revised Ethical Operating Standards.

2. Third Party Personnel. Within 90 days after the Effective Date and annually thereafter by the anniversary of the Effective Date, Merck shall send a letter to each entity employing Third Party Personnel. The letter shall describe Merck's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements and FDA requirements. The letter shall include a description of Merck's Compliance Program. Merck shall attach a copy of its Ethical Operating Standards to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Merck's Ethical Operating Standards and a description of Merck's Compliance Program available to its employees who meet the definition of Third Party Personnel as set forth in Section II.C.9; or (b) represent to Merck that it has and enforces a substantially comparable set of Ethical Operating Standards (or code of conduct) and Compliance Program for its employees who meet the definition of Third Party Personnel as set forth in Section II.C.9.

3. Policies and Procedures. Prior to the Effective Date, Merck established and implemented written Field Policy Letters and Headquarters Guidance Documents related to Promotional Functions and Product Related Functions. Merck also established written policies relating to Government Pricing and Contracting Functions (Customer Contract Management Policies) and MRL Divisional Policies and Global Research and Development Procedures relating to research activities (MRL Policies). Merck's Field Policy Letters, Headquarters Guidance Documents, and Customer Contract Management Policies, and MRL Policies and Corporate Policies shall be collectively known as "Policies and Guidance Documents."

To the extent not already accomplished, within 120 days after the Effective Date, Merck shall ensure that the Policies and Guidance Documents address or shall continue to address:

a. the subjects relating to the Ethical Operating Standards identified in Section III.B.1;

b. appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;

c. appropriate ways to conduct Product Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;

d. appropriate ways to conduct Government Pricing and Contracting Functions in compliance with all applicable Federal health care program and FDA requirements. This includes gathering, calculating, verifying, and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program, the Medicare program, and as otherwise required by Federal or state government directives;

e. appropriate ways to conduct Government Payor Related Functions in compliance with all applicable Federal health care program, state, and other applicable requirements;

f. the materials and information that may be distributed by Merck sales representatives about Government Reimbursed Products and the manner in which Merck sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products. These Policies and Guidance Documents shall require that Merck sales representatives refer all requests for information about non-FDA

approved (off-label) uses of Government Reimbursed Products to GMA;

g. the materials and information that may be distributed by GMA and the mechanisms through, and manner in which, GMA receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Merck's Government Reimbursed Products; the form and content of information disseminated by Merck in response to such requests; and the internal review process for the information disseminated.

   The Policies and Guidance Documents shall include a requirement that GMIO, a subdivision of GMA, develop a database (Inquiries Database) to track all requests for information about Merck's Government Reimbursed Products to GMIO. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Merck's Government Reimbursed Products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting HCP, health care institution (HCI), or other individual or entity; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Merck (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the Merck representative who called on or interacted with the HCP, customer, or HCI, if known;

h. the manner and circumstances under which medical personnel from GMIO interact with or participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Government Reimbursed Products;

i. the development, implementation, and review of call plans for sales representatives who promote Government Reimbursed Products. For each Government Reimbursed Product, the

Policies and Guidance Documents shall require that Merck review the call plans for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call plans. The Policies and Guidance Documents shall also require that Merck modify the call plans as necessary to ensure that Merck is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

j. the development, implementation, and review of plans for the distribution of samples of Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples of Government Reimbursed Products from Merck. The Policies and Guidance Documents shall also require that Merck modify the Sample Distribution Plans as necessary to ensure that Merck is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;

k. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Guidance Documents shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Guidance Documents shall include requirements

about the content and circumstances of such arrangements and events;

l. programs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, and experience-based learning activities, if any. These Policies and Guidance Documents shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

m. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Guidance Documents shall be designed to ensure that Merck's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

n. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.10 above. These Policies and Guidance Documents shall be designed to ensure that Merck's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements;

The Policies and Guidance Documents shall require that: 1) Merck disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection III.B.3.n.4 below, any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose Merck's financial support of the Third Party Educational Activity and to require faculty, speakers, or organizers at such Activity to disclose any financial relationship with Merck; 3) the Third Party Educational Activity has an educational focus; 4) the content, organization, and operation of the Third Party Educational Activity be independent of Merck's control; 5) Merck support only Third Party Educational Activity that is non-promotional in tone/nature; and 6) Merck's support of a Third Party Educational

Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

o. review of promotional materials and information about a Government Reimbursed Product intended to be disseminated outside Merck by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Merck's review and approval process and are elevated when appropriate. The Policies and Guidance Documents shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Guidance Documents shall require that: 1) applicable review committees review all promotional materials prior to the distribution or use of such materials; and 2) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

p. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Guidance Documents shall be designed to ensure that Merck's funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;

q. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives promoting a Government Reimbursed Product. These Policies and Guidance Documents shall: 1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Merck's Government Reimbursed Products; and 2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate off-label promotion of Government Reimbursed Products;

r. the submission of information about any Government Reimbursed Product to any Compendia. This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (e.g., any changes based on Merck's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The Policies and Guidance Documents shall include a requirement that Merck conduct an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by Merck to any Compendia. Merck U.S. compliance personnel or other appropriately trained Merck personnel shall be involved in this review;

s. sponsorship of post-marketing research and investigator-sponsored studies (ISSs) (sometimes also called investigator-initiated studies (IISs)) including the decision to provide financial or other support for the ISSs; the manner in which support is provided; and support for publication of information about the ISSs, including the publication of information about the trial outcomes and results and the uses made of publications relating to ISSs;

t. authorship of any articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all relationships between the author and Merck, the identification of all authors or contributors (including professional writers) associated with a given publication, and the scope and breadth of research results made available to each author or contributor; and

u. disciplinary policies and procedures for violations of Merck's Policies and Guidance Documents, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the Policies and Guidance Documents shall be made available to all Covered Persons.

Appropriate and knowledgeable staff shall be available to explain the Policies and Guidance Documents.

At least annually (and more frequently, if appropriate), Merck shall assess and update, as necessary, the Policies and Guidance Documents. Within 30 days after the effective date of any revisions, any such revised Policies and Guidance Documents shall be made available to all Covered Persons.

C. Training and Education.

1. *Generally*. Prior to the Effective Date, Merck provided two levels of training to Covered Persons who are Merck employees: Awareness Training and Knowledge Training. Merck shall provide or continue to provide Awareness Training and Knowledge Training to all Covered Persons or Relevant Covered Persons, as appropriate, throughout the term of this CIA as set forth in Sections III.C.2-3 below.

2. *Awareness Training.* Merck shall provide annual training to Covered Persons on the Ethical Operating Standards through an in-person or computer-based training program. Prior to the Effective Date, Merck established a training program known as "Awareness Training" which covered and shall continue to cover throughout the term of this CIA, the following:

a. Merck's Compliance Program (including the Ethical Operating Standards); and

b. Merck's obligations under the CIA.

To the extent not already provided to Covered Persons 180 days prior to the Effective Date, within 120 days after the Effective Date, Merck shall provide one hour of Awareness Training to, and obtain an Acknowledgement (as set forth in Section III.C.5) from, each Covered Person.

With respect to employees who are entering a Covered Persons position for the first time (*i.e.*, new Covered Persons) on or after the Effective Date, Merck shall conduct two hours of Awareness Training, within 30 days after such person's entering such position or within 120 days after the Effective Date (whichever is later), which shall cover:

c. Merck's Compliance Program (including the Ethical Operating Standards) and obligations under the CIA; and

d. in general, the proper methods of engaging in the Covered Functions in a manner compliant with Federal health care program and FDA requirements.

3. *Knowledge Training*. Merck shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training is known as "Knowledge Training."

Each Relevant Covered Person engaged in Promotional Functions and/or Product Related Functions shall receive Knowledge Training applicable to their specific job functions in addition to the Awareness Training described above. To the extent not covered in Awareness Training, this Knowledge Training shall include a discussion of:

a. all applicable Federal health care program requirements and FDA requirements relating to Promotional Functions and/or Product Related Functions (as applicable to the individual);

b. all applicable FDA requirements relating to Promotional Functions and/or Product Related Functions (as applicable to the individual);

c. all Merck policies, procedures, and other requirements applicable to Promotional Functions and/or Product Related Functions;

d. the personal obligation of each individual involved in Promotional Functions and/or Product Related Functions to comply with applicable Federal health care program and FDA requirements and other applicable legal requirements;

e. the legal sanctions for violations of the Federal health care program requirements or FDA requirements; and

f. examples of proper and improper practices related to Promotional Functions and/or Product Related Functions.

For the first Reporting Period, each Relevant Covered Person engaged in Government Pricing and Contracting Functions shall receive Knowledge Training applicable to their specific job functions in addition to the Awareness Training described above. To the extent not covered in Awareness Training, this Knowledge Training shall include a discussion of:

g. Merck's systems and processes relating to Government Pricing and Contracting Functions;

h. all applicable Federal health care program requirements relating to Government Pricing and Contracting Functions;

i. Merck's systems for gathering relevant data and calculating, verifying, and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Drug Rebate Program, the Medicare Program, or any other Federal or state government price reporting requirement;

j. the personal obligation of each individual involved in Government Pricing and Contracting Functions to ensure that all reported pricing and other information is accurate;

k. the legal sanction for violations of Federal health care program requirements; and

l. examples of proper and improper practices related to Government Pricing and Contracting Functions.

Each Relevant Covered Person engaged in Government Payor Related Functions shall receive Knowledge Training applicable to their specific job functions in addition to the Awareness Training described above. This Knowledge Training shall include a discussion of:

m. Merck's systems, processes, policies, and procedures relating to Government Payor Related Functions;

n. all applicable Federal health care program requirements and other requirements relating to Government Payor Related Functions;

o. the personal obligation of each individual involved in Government Payor Related Functions to ensure that all information provided or reported to Government Payors (or to PBMs or other individuals or entities under contract with, or acting on behalf of the payors) is accurate;

p. the legal sanction for violations of Federal health care program requirements and other applicable requirements; and

q. examples of proper and improper practices related to Government Payor Related Functions.

To the extent not already accomplished within 180 days prior to the Effective Date, within 120 days after the Effective Date, Merck shall provide 2 hours of Knowledge Training to, and obtain an Acknowledgement (described in Section III.C.5) from, each Relevant Covered Person in accordance with the provisions set forth above in this Section III.C.3. After receiving the Knowledge Training described above during the first Reporting Period, each Relevant Covered Person shall receive at least 2 hours of Knowledge Training, in addition to 1 hour of Awareness Training, in each of the subsequent Reporting Periods.

Individuals who become Relevant Covered Persons on or after the Effective Date (*i.e.*, new Relevant Covered Persons) shall receive the Knowledge Training and provide an Acknowledgement within 30 days after becoming a Relevant Covered Person or within 120 days after the Effective Date, whichever is later. A Relevant Covered Person who has completed the Knowledge Training shall review the work of a new Relevant Covered Person, to the extent that the work relates to Covered Functions until such time as the new Relevant Covered Person completes his or her Knowledge Training.

4. *Board Member Training*. Within 120 days after the Effective Date, Merck shall provide at least two hours of training to each member of the Board of Directors, in addition to the Awareness Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a board member or within 120 days after the Effective Date, whichever is later.

5. Acknowledgement. Each Covered Person who is required to complete Awareness Training and each Relevant Covered Person who is required to also complete Knowledge Training shall acknowledge, in writing or in electronic form, if applicable, that he or she has received such training and the date such training was received. The Compliance Officer (or designee) shall retain these Acknowledgements, along with all course materials. These shall be made available to OIG, upon request.

6. *Qualifications of Trainer.* Persons responsible for providing the Awareness Training and the Knowledge Training shall be knowledgeable about the subject area of the training.

7. *Update of Training.* Merck shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information.

8. *Computer-based Training.* Merck may provide the training required under this CIA through appropriate computer-based training approaches. If Merck chooses to provide computer-based training, it makes and shall continue to make available appropriately qualified and knowledgeable trainers to answer questions or provide additional information to the individuals receiving such training. If Merck chooses to provide computer-based Awareness or Knowledge Training, all applicable requirements to provide a number of "hours" of training as set forth in this Section III.C may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization*. Within 120 days after the Effective Date, Merck shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to

perform reviews to assist Merck in assessing and evaluating its Promotional Functions, Product Related Functions, Government Payor Related Functions, and Government Pricing and Contracting Functions. The applicable requirements relating to the IRO are outlined in Appendix C to this CIA, which is incorporated by reference.

Each IRO engaged by Merck shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Merck, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess Merck's systems, processes, policies, procedures, and practices relating to Promotional Functions, Product Related Functions, Government Payor Related Functions and Government Pricing and Contracting Functions (IRO Reviews).

b. *Frequency and Brief Description of Reviews.*

(i) Medicaid Drug Rebate Review. As set forth more fully in Appendix A, for the first Reporting Period and the first quarter of the second Reporting Period, the IRO shall perform reviews designed to assess and evaluate Merck's Government Pricing and Contracting Functions (Medicaid Drug Rebate Review). The Medicaid Drug Rebate Review shall consist of reviews of samples of transactions relevant to the Average Manufacturer Prices and Best Prices reported to CMS for purposes of the Medicaid Drug Rebate Program.

(ii) Reviews relating to Other Covered Functions: As set forth more fully in Appendix B, the IRO shall conduct Systems Reviews and a Transactions Reviews relating to Promotional Functions, Product Related Functions, and Government Payor Related Functions. The Systems Review shall assess Merck's systems, processes, policies, and procedures relating to Promotional Functions, Product Related

Functions, and Government Payor Related Functions. If there are no material changes in Merck's relevant systems, processes, policies, and procedures, the IRO Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Merck materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

The Transactions Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

In addition, each Transactions Review shall also include a review of up to three additional areas or practices of Merck identified by the OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Merck and may consider internal audit work conducted by Merck, the Government Reimbursed Product portfolio, the nature and scope of Merck's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, Merck may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Merck's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify Merck of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Merck shall submit an audit

work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

d. *Retention of Records*. The IRO and Merck shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Merck) related to the IRO Reviews.

2. *IRO Review Reports*. The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A and B.

3. *Validation Review*. In the event OIG has reason to believe that: (a) any of Merck's IRO Reviews fail to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Merck shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Merck's final Annual Report shall be initiated no later than one year after Merck's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Merck of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Merck may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. Merck agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Merck prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Merck a certification or sworn affidavit that it has evaluated its professional

independence and objectivity with regard to the applicable IRO Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Prior to the Merck Effective Date, Merck established a multi-faceted Disclosure Program that enabled individuals to raise concerns related to any potential unethical or illegal behavior associated with Federal health care programs, FDA requirements or Merck's policies, procedures, or practices confidentially to the Office of Ethics. The Disclosure Program includes Merck's AdviceLine and Ombudsman Program, mechanisms that individuals can access and for which appropriate confidentiality is maintained. Merck's AdviceLine is a toll-free telephone line staffed by a third-party that is available 24 hours a day, seven days a week. Merck's Ombudsman Program is staffed by individuals in the Office of Ethics. Merck shall continue this Disclosure Program during the term of this CIA. Merck publicizes, and shall continue to publicize, the existence of the Disclosure Program in the Code of Conduct, the Ethical Operating Standards, through training sessions, and by posting information in prominent common areas of Merck's headquarter facilities, on Merck's intranet sites, and on Merck's external website.

During the term of this CIA, the Disclosure Program shall continue to emphasize confidentiality and a nonretribution, nonretaliation policy. Merck makes and shall continue to make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Merck conducts and shall continue to conduct an internal review of the allegations set forth in the disclosure. Merck shall ensure that proper follow-up is conducted. Disclosures made through the AdviceLine and the Ombudsman Program are investigated, as appropriate, by a designee from the Office of Ethics, who then determines the appropriate resolution in coordination with the appropriate parties, including the Compliance Officer or designee.

Merck maintains, and shall continue to maintain, a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. This disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

2. *Screening Requirements.* Merck shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. as part of the hiring or contracting process, Merck shall require all prospective and current Covered Persons to disclose whether they are Ineligible Persons and shall screen potential Covered Persons against the Exclusion Lists prior to engaging their services.

b. To the extent not already accomplished within 180 days prior to the Effective Date, Merck shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Merck shall maintain a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section III.F affects Merck's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Merck understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Merck may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Merck meets the requirements of Section III.F.

3. *Removal Requirement*. If Merck has actual notice that a Covered Person has become an Ineligible Person, Merck shall remove such Covered Person from responsibility for, or involvement with, Merck's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If Merck has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Merck shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Merck shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Merck conducted or brought by a U.S. governmental entity or its agents involving an allegation that Merck has committed a crime or has engaged in fraudulent activities in the U.S. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Merck shall also provide written

notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reportable Events. The terms of this Section III.H shall become effective upon the date on which the last signatory to the CIA signs the document.

1. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products;

c. an FDA Warning Letter issued to Merck;

d. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

e. the filing of a bankruptcy petition by Merck.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If Merck determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Merck shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.H.1.a-d*. For Reportable Events under Sections III.H.1.a-d, the report to OIG shall include:

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;

b. a description of Merck's actions taken to correct the Reportable Event; and

c. any further steps Merck plans to take to address the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.H.1.e*. For Reportable Events under Section III.H.1.e, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

I. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Merck and the FDA that materially discusses Merck's or a Covered Person's actual or potential unlawful or improper promotion of Government Reimbursed Products (including any improper dissemination of information about off-label indications), Merck shall provide a copy of the report, correspondence, or communication to the OIG. Merck shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, Merck shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales representatives' interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: 1) a Speaker Monitoring Program; 2) direct field observations (Observations) of sales representatives; and 3) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to speaker programs, Merck shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use Merck approved materials and may not directly or indirectly promote the product for off-label uses.) Merck shall maintain a centralized electronic system through which all speaker programs are administered. This system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed system based on a fair-market value analysis conducted by Merck. Merck shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, Merck shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. Merck shall require certified evaluations by sales representatives or other Merck personnel regarding whether a speaker program complied with Merck requirements, and in the event of non-compliance, Merck shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, Merck shall institute a Speaker Monitoring Program under which Merck compliance or other appropriately trained personnel who are independent from the functional area being monitored shall attend 150 speaker programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Merck representative activities during the program to assess whether the program was conducted in a manner consistent with Merck's Policies and Guidance Documents. Merck shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations*. As a component of the FFMP, Merck U.S. compliance personnel or other appropriately trained personnel shall conduct observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable Federal healthcare or FDA requirements and with Merck's Policies and Guidance Documents. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of

directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by Merck U.S. compliance personnel both on a risk-based targeting approach and on a sampling approach and the selection of the Observations shall include each therapeutic area and actively promoted Government Reimbursed Product, and be conducted across the United States. At the completion of each Observation, Merck U.S. compliance personnel or other appropriately trained personnel shall prepare a report which includes:

1) the identity of the sales representative;
2) the identity of the Merck compliance personnel or other appropriately trained personnel;
3) the date and duration of the Observation;
4) the product(s) promoted during the Observation;
5) an overall assessment of compliance with Merck policy; and
6) the identification of any potential off-label promotional activity or other improper conduct by the sales representative.

Merck U.S. compliance personnel or other appropriately trained personnel shall conduct at least 50 Observations during each Reporting Period.

3. *Records Reviews*. As a component of the FFMP, Merck shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs in order to identify potential or actual compliance violations. For each Reporting Period, Merck shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products and a sampling of the representatives promoting those Government Reimbursed Products in every separate region. The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the Government Reimbursed Products based on information about the Government Reimbursed Products provided by Merck, upon request by the OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, Merck shall select the three Government Reimbursed Products to be reviewed.

These Records Reviews shall include the monitoring and review of: 1) records and systems relating to sales representatives' interactions with HCPs and HCIs (including records from any available electronic detailing system for the particular sales

representative, sales communications from managers, sample distribution records, and expense reports); 2) requests for medical information about, or inquiries relating to, Government Reimbursed Products; 3) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales representatives' interactions with HCPs and HCIs; 4) sales representatives' call notes; 5) sales representatives' e-mails and other electronic records; and 6) recorded results of the Observations of sales representatives and applicable notes or information from the sales representatives' managers.

4. *Reporting and Follow-up*. Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate. In the event that a potential violation of Merck's Policies and Guidance Documents or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, Merck shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during a Speaker Program Audit, Observation and/or Records Review and any corrective action shall be recorded in the files of the U.S. Compliance Department.

Merck shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Merck also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Merck took as a result of such determinations. Merck shall make the Observation reports for all other Observations available to the OIG upon request.

K. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 120 days after the Effective Date Merck shall develop and implement a monitoring program for the following types of activities: 1) consultant arrangement activities; 2) research-related activities; 3) publication activities; and 4) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities*. To the extent that Merck engages U.S.-licensed and based HCPs or HCIs for services that relate to Promotional Functions or Product Related Functions other than for speaker programs, research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. Merck shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed system based on a fair-market value analysis conducted by Merck.

To the extent not already accomplished, within 120 days after the Effective Date, Merck shall establish a process to develop annual budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following annual period. The annual Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. Merck's U.S. compliance personnel or other appropriately trained Merck personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable Merck Policies and Guidance Documents.

To the extent not already accomplished, within 120 days after the Effective Date, Merck shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Merck U.S. compliance personnel or other appropriately trained Merck personnel.

To the extent not already accomplished, within 120 days after the Effective Date, Merck shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Merck received the work product generated by the Consultant.

Within 120 days after the Effective Date, Merck shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 50 Consultant arrangements with HCPs. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. Merck U.S. compliance personnel or other appropriately trained Merck personnel conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Merck's Policies and Guidance Documents. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate.

2. *Research-Related Activities*. To the extent that Merck engages U.S.-based and licensed HCPs or HCIs to conduct Phase IV, post-marketing clinical studies such HCPs and HCIs shall be referred to collectively as "Researchers". Merck shall require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed including any publications related to the research, any fees to be paid, and compliance obligations for the Researchers. Researchers shall be paid according to a centrally managed system that is determined based on a fair-market value analysis conducted by Merck.

To the extent not already accomplished, within 120 days after the Effective Date, Merck shall establish an annual budgeting plan for Researchers that identifies the business or scientific need for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. Merck U.S. compliance personnel or other appropriately trained Merck personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with Merck Policies and Guidance Documents.

To the extent not already accomplished, within 120 days after the Effective Date, Merck shall establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided

by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Merck U.S. compliance personnel or other appropriately trained Merck personnel.

To the extent that Merck provides financial or other support to U.S.-licensed HCPs or HCIs for IISs/ISSs regarding Government Reimbursed Products, such HCPs and HCIs shall be referred to as "Investigators." Merck shall require all Investigators to enter into written agreement describing the scope of the work to be performed including any publications related to the research, any fees to be paid, and the compliance obligations of the Investigators. Investigators shall be paid based on a fair market value analysis conducted by Merck.

To the extent not already accomplished, within 120 days of the Effective Date, Merck shall establish a process for review and approval of ISSs/IISs. The process shall require consideration of the business or scientific need for the research by the potential Investigators as well as review of specific details regarding the research arrangements (including, for example, information regarding the proposed research to be done and the type of work to be generated).

To the extent not already accomplished, within 120 days after the Effective Date, Merck shall amend its policies and procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was engaged.

Within 120 days after the Effective Date, Merck shall establish a Researcher and Investigator Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher and Investigator Program Audits) of at least 15 Researcher arrangements and 15 Investigator arrangements with HCPs or HCIs. The Researcher and Investigator Monitoring Program shall review Researcher and Investigator arrangements both on a risk-based targeting approach and on a sampling approach. Merck U.S. compliance personnel or other appropriately trained Merck personnel conducting the Researcher and Investigator Program Audits shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were supported by Merck and performed by the Researchers and/or Investigators in a manner consistent with Merck's

Policies and Guidance Documents. Results from the Researcher and Investigator Program Audits, including identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate.

3. *Publication Activities.* Prior to entering into this CIA, Merck voluntarily adopted a Publications Protocol Transparency Initiative (PPTI), pursuant to which Merck voluntarily provides the protocol and statistical analysis plan (SAP) with any manuscript that Merck submits to a biomedical journal involving Merck-sponsored clinical trials of any investigational or approved medicine or vaccine. These materials are used by the journal editors and peer reviewers in the evaluation of the manuscript submitted by Merck. In addition, the PPTI provides that, if the manuscript is accepted for publication, the journals at their sole discretion may post the key sections of the protocol and SAP to their websites for public scrutiny. Merck agrees and represents that it will continue to engage in the PPTI or equivalent initiative throughout the duration of this CIA.

4. *Medical Education Grant Activities.* Merck represents that it has established a grants office within its GMA Department as the exclusive mechanism through which requestors may seek or be awarded grants for independent medical education activities funded by GHH-U.S. Merck also represents that it has established a grants committee within MV as the exclusive mechanism through which requestors may seek grants for independent medical education activities funded by MV.

Merck represents that its sales and marketing departments have no involvement in, or influence over, the review and approval of U.S. medical education grants. Grant requests shall be submitted through an on-line process and requests are processed in accordance with standardized criteria developed by the grants office. Merck shall continue the medical education grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

To the extent not already accomplished, within 120 days after the Effective Date, Merck shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 medical education grants funded by GHH-US or MV. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. Merck U.S. compliance personnel or other appropriately trained Merck personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents,

contracts, payments and materials relating to the grant office's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with Merck's Policies and Guidance Documents. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate.

5. *Follow Up Reviews and Reporting.* In the event that a potential violation of Merck's Policies and Guidance Documents or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the Non-Promotional Monitoring Program, Merck shall investigate the incident consistent with established Policies and Guidance Documents or other relevant processes for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the U.S. Compliance Department.

Merck shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, Merck also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Merck's requirements or Policies and Guidance Documents, and a description of the action(s) that Merck took as a result of such determinations. Merck shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

L. Notice to Health Care Providers and Entities. Within 90 days after the date on which the last signatory to the CIA signs the document, Merck shall send, by first class mail, postage prepaid and return receipt requested, a notice containing the language set forth below to all HCPs and HCIs that Merck currently details. This notice shall be dated and shall be signed by Merck's President. The body of the letter shall state the following:

As you may be aware, Merck recently entered into a global civil, criminal,

and administrative settlement with the United States and individual states in connection with the promotion and use of one of its products. This letter provides you with additional information about the settlement, explains Merck's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that Merck unlawfully promoted Vioxx for a use not approved by the Food & Drug Administration (FDA) and that Merck engaged in other improper conduct relating to Vioxx. To resolve these matters, Merck pled guilty to a misdemeanor criminal violation of the Federal Food, Drug & Cosmetic Act (FDCA) and agreed to pay a criminal fine of $321 million. In addition, the Government alleged that Merck violated the False Claims Act and Merck entered into a civil settlement to resolve these allegations pursuant to which Merck agreed to pay $629 million to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[Merck shall include a link to the USAO, OCL, and Merck websites in the letter.]**

As part of the federal settlement, Merck also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at http://oig.hhs.gov/fraud/cia/index.html. Under this agreement, Merck agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Merck's representatives to Merck's Compliance Department or the Food & Drug Administration (FDA).

Please call Merck at **1-800-883-5285** or **contact us at BPandC@merck.com** if you have questions about the settlement referenced above or to report any instances in which you believe that an Merck representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report such instances of any improper promotion of a Merck product to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to **1-800-526-7736.**

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notice shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Merck shall provide to the OIG a summary of the calls and messages received.

M. Reporting of Physician Payments.

1. *Reporting of Payment Information.*

Quarterly Reporting: On or before June 1, 2012, Merck shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.M.2) directly or indirectly from Merck during the first quarter of 2012 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, Merck shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

Annual Reporting: On or before March 1, 2013, and 60 days after the end of each subsequent calendar year, Merck shall post on its website a report of the cumulative value of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from Merck during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.M shall include a complete list of all individual physicians or Related Entities to whom or which Merck made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician has provided to Merck for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

2. *Definitions and Miscellaneous Provisions.*

(i) Merck shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. Merck shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Merck to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

(ii) For purposes of Section III.M.1, "Payments" is defined to include all "payments or transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Merck would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by Merck or by a vendor retained by Merck to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iii) For purposes of its annual and quarterly website postings as described above, and only with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act, Merck may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(iv) The term "Payments" does not include transfers of value or other items that are not included in or are excluded from the definition of "payment" as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

(v) For purposes of this Section III.M, the term "Related Entity" is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

N. Other Transparency/Disclosure Initiatives.

Merck represents that it posts on its company website the following information with respect to both grants and charitable contributions: annual disclosure of the grants subject to monitoring pursuant to Section III.K.4 of this CIA and annual disclosure of philanthropic contributions made through the Office of Corporate Philanthropy and The Merck Company Foundation. Merck shall continue to post (and provide updates to) the above-described information about grants and charitable contributions throughout the term of this CIA. Merck shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of grants and charitable contributions or posting of the above-referenced information relating to such funding.

Merck represents that it requires all Consultants (as defined in Section III.K.1) to fully comply with all applicable disclosure obligations relating to their relationship with Merck that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. Merck shall continue this requirement throughout the term of this CIA. Merck represents that within 120 days after the Effective Date, Merck shall, if necessary, amend its policies relating to Consultants to explicitly state that Merck requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Merck that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 150 days following the Effective Date, Merck shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. Merck shall continue these disclosure requirements throughout the term of this CIA.

Merck represents that it expects all Authors of biomedical manuscripts to fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Merck and to disclose any

potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 120 days after the Effective Date, Merck, if necessary, shall amend its policies relating to Authors to explicitly state Merck's requirement about full disclosure by Authors consistent with the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts with Authors and in any new contracts with Authors entered into after 120 days following the Effective Date, Merck shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with Merck, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

Within 120 days after the Effective Date, Merck shall register all clinical studies and report results of such clinical studies on the National Institutes of Health (NIH) sponsored website (www.clinicaltrials.gov) in compliance with all current federal requirements. Merck shall continue to comply with Federal health care program requirements, or other applicable U.S. requirements relating to the registration and results reporting of clinical studies throughout the term of this CIA. In addition, if there is a change in Federal health care program requirements, FDA requirements, NIH requirements, or other applicable requirements relating to registration and results reporting of clinical study information, Merck shall fully comply with such requirements.

Within 120 days after the Effective Date, Merck shall post or make available information on its company website about postmarketing requirements (PMRs) as defined by the FDA. The Merck website or links included therein shall provide access to general information about the PMR process, descriptions of ongoing Merck studies, and information about the nature and status of FDA post-marketing commitments. Merck shall continue to post or make available the above-described information about PMRs on its website or links included therein throughout the term of this CIA.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the date on which the last signatory to the CIA signs the document, Merck changes locations or closes a business unit or location related to or engaged in any of the Covered Functions, Merck shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the date on which the last signatory to the CIA signs the document, Merck purchases or establishes a new business unit or location related to or engaged in any of the Covered Functions, Merck shall notify OIG no later than five days after the date that the purchase or establishment of the new business unit or location is publicly disclosed by Merck. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Merck currently submits claims (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the date on which the last signatory to the CIA signs the document, Merck proposes to sell any or all of its business units or locations that are subject to this CIA, Merck shall notify OIG of the proposed sale at no later than five days after the sale is publicly disclosed by Merck. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. MODIFICATION AND ANNUAL REPORTS

A. Modification Report. Within 150 days after the Effective Date, Merck shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA to the extent that this CIA has imposed new requirements that have resulted in implementation of new processes, procedures, policies, and other changes (Modification Report), as detailed below. The Modification Report shall, at a minimum, include:

1. the names of the members of the Board of Directors referenced in Section III.A.4;

2. the names and positions of the Certifying Employees required by Section III.A.5;

3. a summary or copy of all Policies and Guidance Documents regarding the requirements of Sections III.J, III.K, III.M, and III.N;

4. an index of the Policies and Guidance Documents required by Section III.B that were previously not required under the Unified CIA;

5. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to participate in training and complete the Acknowledgements required by Section III.C.5, percentage of individuals who completed the training and Acknowledgements, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. if the IRO is different from the IRO used under the Unified CIA, the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) information to demonstrate that the IRO has the qualifications outlined in Appendix C; (d) a summary and description of any and all current and prior engagements and agreements between Merck and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Merck;

7. a certification by the Compliance Officer that the notice required by Section III.L was mailed to each HCP and HCI, the number of HCPs and HCIs to whom the notice was mailed, a sample copy of the notice required by Section III.L, and a summary of the calls or messages received in response to the notice;

8. a certification from the Compliance Officer that, if required under Section III.M and to the best of his/her knowledge, information regarding Payments has been posted on Merck's website as required by Section III.M; and

9. the certifications required by Section V.C.2.

B. Annual Reports. Merck shall submit to OIG annually a report with respect to the status of, and findings regarding, Merck's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board, or the names or titles of the Certifying Employees described in Sections III.A.2-5;

2. a copy of the resolution by the Board required by Section III.A.4;

3. the number of individuals required to review Merck's Ethical Operating Standards and complete the Acknowledgement required by Section III.B.1, the percentage of individuals who have completed such Acknowledgement, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. a) a copy of the letter (including all attachments) required by Section II.C.9 and III.B.2 sent to each party employing Third Party Personnel; b) a list of all such existing co-promotion and other applicable agreements; and c) a description of each entity's response to Merck's letter;

5. a summary or copies of any significant changes or amendments to the Policies and Guidance Documents required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

6. to the extent not provided in the Modification Report, the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of live training sessions; and

b. the number of individuals required to participate in training and complete the Acknowledgements required by Section III.C.5, percentage of individuals who completed the training and Acknowledgements, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;

8. Merck's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

9. a summary and description of any and all current and prior engagements and agreements between Merck and the IRO, (if different from what was submitted as part of the Modification Report);

10. a certification from the IRO regarding its professional independence and objectivity with respect to Merck;

11. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs or Government Reimbursed Products;

12. any changes to the process by which Merck fulfills the requirements of Section III.F regarding Ineligible Persons;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

15. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a

description of the matter and the status of the matter;

16. a summary of the FFMP and the results of the FFMP required by Section III.J, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Merck took as a result of such determinations;

17. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.K, including detailed description of any identified instances in which it was determined that the activities violated Merck's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Merck took as a result of such determinations;

18. a summary of the calls and messages received in response to the notice required by Section III.L and the disposition of those calls and messages;

19. a description of all changes to the most recently provided list of Merck's locations (including addresses); the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

20. a description of any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.3.r; and a description of all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia evaluated during the annual review described in Section III.B.3.r; and

21. the certifications required by Section V.C and, for the first two Reporting Periods, the Certification relating to Medicaid Rebate Policies and Procedures as set forth in Appendix D.

The first Annual Report shall be received by OIG no later than 135 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. Certifying Employees: In each Annual Report, Merck shall include the certifications of Certifying Employees as required by Section III.A.5;

2. Compliance Officer: In the Modification Report and in each Annual Report, Merck shall include the following individual certification by the Compliance Officer:

1. to the best of his or her knowledge, except as otherwise described in the report, Merck is in compliance with the requirements of this CIA;

2. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;

3. Merck's: 1) Policies and Guidance Documents as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Merck's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Merck have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Guidance Documents to ensure that legal, medical, and regulatory concerns have been addressed by Merck and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of Merck's Policies and Guidance Documents, templates for standardized contracts, and training materials for Section III.C, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

4. Merck's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.i) and, for each product the call plans were found to be consistent with Merck's policy objectives as referenced above in Section III.B.3.i.

D. Designation of Information. Merck shall clearly identify any portions of its

submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Merck shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG: Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Merck: Lauran S. D'Alessio
Vice President,
Compliance Officer
Merck & Co., Inc.
WS-2BC-40
One Merck Drive
Whitehouse Station, NJ 08889
Telephone: 908-423-4321
Facsimile: 908-735-1162

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Merck may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Merck's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Merck's locations for the purpose of verifying and evaluating: (a) Merck's compliance with the terms of this CIA; and (b) Merck's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Merck to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Merck's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Merck shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Merck's employees may elect to be interviewed with or without a representative of Merck present.

VIII. DOCUMENT AND RECORD RETENTION

Merck shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Merck prior to any release by OIG of information submitted by Merck pursuant to its obligations under this CIA and identified upon submission by Merck as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Merck shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Merck is expected to fully and timely comply with all of its CIA obligations. The breach and default remedies available to the OIG under this Section X do not preempt any actions that individual States may take against Merck under any applicable settlement agreement or consent decree between the State and Merck.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Merck and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Merck fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. the Board compliance obligations, including the resolution from the Board;

c. a written Code of Conduct;

d. written Policies and Guidance Documents;

e. the training of Covered Persons, Relevant Covered Persons, and Board Members;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements;

h. notification of Government investigations or legal proceedings;

i. reporting of Reportable Events;

j. notification of written communications with FDA as required by Section III.I;

k. a program for FFMP as required by Section III.J;

l. a program for Non-Promotional Monitoring Program as required by Section III.K;

m. notification to HCPs and HCIs as required by Section III.L; and

n. posting of any Payments as required by Section III.M.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Merck fails to engage and use an IRO, as required in Section III.D and Appendices A-C.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Merck fails to submit the Modification Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Merck fails to submit any IRO Review Report in accordance with the requirements of Section III.D and Appendices A-B.

5. A Stipulated Penalty of $1,500 for each day Merck fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Merck fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Merck as part of its Modification Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Merck fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Merck stating the specific grounds for its determination that Merck has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Merck shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Merck receives

this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. Merck may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Merck fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Merck receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Merck has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Merck of: (a) Merck's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, Merck shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Merck elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Merck cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination*. Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Merck has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by Merck to report a Reportable Event and take corrective action as required in Section III.H;

c. a failure to engage and use an IRO in accordance with Section III.D and Appendices A-C;

d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
e. a failure of the Board to issue a resolution in accordance with Section III.A.4.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Merck constitutes an independent basis for Merck's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Merck has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Merck of: (a) Merck's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure*. Merck shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Merck is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30 day period, but that: (i) Merck has begun to take action to cure the material breach; (ii) Merck is pursuing such action with due diligence; and (iii) Merck has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, Merck fails to satisfy the requirements of Section X.D.3, OIG may exclude Merck from participation in the Federal health care programs. OIG shall notify Merck in writing of its determination to exclude Merck (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Merck's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Merck may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to Merck of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Merck shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42

of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Merck was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Merck shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Merck to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Merck requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether Merck was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Merck had begun to take action to cure the material breach within that period; (ii) Merck has pursued and is pursuing such action with due diligence; and (iii) Merck provided to OIG within that period a reasonable timetable for curing the material breach and Merck has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Merck, only after a DAB decision in favor of OIG. Merck's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Merck upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Merck may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Merck shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the

ALJ or DAB. If the DAB finds in favor of Merck, Merck shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Merck and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Merck;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. The undersigned Merck signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF MERCK & CO., INC.

/Bruce Kuhlik/ 11/22/11

BRUCE KUHLIK DATE
Executive Vice President and General Counsel
Merck & Co., Inc.

/Lauran D'Alessio/ 11/22/11

LAURAN D'ALESSIO DATE
Vice President and Compliance Officer
Merck & Co., Inc.

/John Rah/ 11/22/11

JOHN RAH, ESQ. DATE
Morgan Lewis & Bockius LLP
Counsel for Merck & Co., Inc.

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Gregory E. Demske/ 11/21/11

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Mary E. Riordan/ 11/22/11

MARY E. RIORDAN
Senior Counsel
Office of Counsel to the Inspector General
U. S. Department of Health and Human Services

DATE

/Geeta W. Kaveti/ 11/21/11

GEETA W. KAVETI
Associate Counsel
Office of Counsel to the Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A TO CIA FOR MERCK & CO, INC.

MEDICAID DRUG REBATE REVIEW

I. Medicaid Drug Rebate Review – General Description

As specified more fully below, Merck shall retain an Independent Review Organization (IRO) to perform reviews to assist Merck in assessing and evaluating its compliance with the requirements for Average Manufacturer Price (AMP) and Best Price (BP) under the Medicaid Drug Rebate Program. In order to conduct the Medicaid Drug Rebate Review, the IRO shall review samples of transactions to assess whether Merck is calculating AMPs and BPs consistent with the requirements of the Medicaid Drug Rebate Program. The Medicaid Drug Rebate Review shall consist of two parts, the "AMP Reported Prices Procedures" and the "BP Reported Prices Procedures." The IRO shall conduct the Medicaid Drug Rebate Review for the first Reporting Period and the first two quarters of the second Reporting Period.

II. Medicaid Drug Rebate Review

A. Party(ies) Conducting the Medicaid Drug Rebate Review

Merck annually conducts audits relating to Government Pricing and Contracting Functions, and Merck expects to continue such audits during the specified term set forth in the CIA. At its option, Merck may provide a detailed description of its planned annual audits to the OIG 60 days prior to the beginning of each new Reporting Period. Merck may propose to the OIG that its planned internal audits be substituted for a portion of the Medicaid Drug Rebate Review outlined below in this Section II for the applicable Reporting Period.

If the OIG agrees to permit certain of Merck's internal audit work for a given Reporting Period to be substituted for a portion of the Medicaid Drug Rebate Review, such internal audit work would, at a minimum, be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional direction and specification about the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Merck in its internal audits and shall prepare a report based on its review.

The OIG retains sole discretion over whether to allow Merck's internal audit work to be substituted for a portion of the IRO's Medicaid Drug Rebate Review. In

making its decision, the OIG agrees to consider, among other factors, the nature and scope of Merck's planned internal audit work, the results of the Medicaid Drug Rebate Review(s) during prior Reporting Period(s), and Merck's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Merck's request to permit Merck's internal audit work to be substituted for a portion of the Medicaid Drug Rebate Review in a given Reporting Period, Merck shall engage the IRO to perform the Review as outlined below in this Section II.

B. General Description and Definitions

For each applicable Reporting Period, the IRO shall select and review a sample of transactions from a randomly selected quarter within that Reporting Period to determine whether Merck calculated and reported AMP and BP consistent with the requirements of the Medicaid Drug Rebate Program. The selected quarter shall be identified through the use of the OIG's Office of Audit Services Statistical Sampling Software known as "RAT-STATS" or through the use of another method of random sampling acceptable to the OIG.

For purposes of the AMP Reported Prices Review, the following definitions shall apply:

1. "Actual Transaction Types" are defined as those transactions that are finalized at the time of the sale. As of the Effective Date of the Unified CIA, Merck had two categories of Actual Transaction Types, namely direct sales and on-invoice discounts. Each of these categories shall be considered a universe of Actual Transaction Types from which the IRO shall draw samples as detailed below in Section II.C.1. Each Transaction within the Actual Transaction Types group shall be referred to as an "Actual Transaction." If, during the term of the CIA, Merck establishes additional categories of Actual Transaction Types, each of the new categories shall be considered an additional universe of transactions from which samples of Actual Transactions shall be selected for purposes of the AMP Reported Prices Procedures.

2. "Lagged Transaction Types" are defined as those transaction types that are processed on a lagged basis. As of the Effective Date of the Unified CIA, Merck had two categories of Lagged Transaction Types, namely indirect sales, and adjustments or discounts available on a lagged basis. Each of these categories shall be considered a universe of Lagged Transaction Types from which the IRO shall draw samples as detailed below in Sections II.C.1. Each Transaction within the Lagged Transaction Types

group shall be referred to as a "Lagged Transaction." If, during the term of the CIA, Merck establishes additional categories of Lagged Transaction Types, each of those new categories shall be considered an additional universe of transactions from which samples of Lagged Transactions shall be selected for purposes of the AMP Reported Prices Procedures.

The Actual Transaction Types and Lagged Transaction Types shall be referred to hereafter as "Transaction Types".

C. AMP Reported Prices Procedures

1. Identification and Review of Transaction Types.

For each applicable Reporting Period, the IRO shall review a sample of transactions to determine whether Merck calculated and reported AMP in accordance with the requirements of the Medicaid Drug Rebate Program (AMP Reported Prices Procedures). The IRO shall conduct its AMP Reported Prices Procedures by selecting and testing samples from each universe of the applicable Transaction Types, as identified by Merck, for the selected quarter within the Reporting Period. The IRO shall test a discovery sample of 30 Transactions from each universe of Transaction Types for the selected quarter.

a) Actual Transactions

For each universe of Actual Transaction Types, the IRO shall randomly select a discovery sample and, with regard to the sample, shall determine:

i) Whether the Actual Transactions are supported by source documents; and

ii) Whether Merck included or excluded each Actual Transaction in the AMP calculation in accordance with Medicaid Drug Rebate Program requirements.

b) Lagged Transactions

For each universe of Lagged Transaction Types, the IRO shall randomly select a discovery sample and, with regard to the sample, shall determine:

i) Whether the Lagged Transaction amounts were calculated in accordance with Merck's policies, procedures, and methodologies and (where applicable) the Medicaid Drug Rebate Program requirements, and were supported by relevant commercial arrangements or other source documentation; and

ii) Whether the Lagged Transactions were included in or excluded from the AMP calculation in accordance with Medicaid Drug Rebate Program requirements.

2. Additional Investigation of Transactions

If any discovery sample defined in Section II.C.1 reveals a net dollar Error Rate of 5% or greater, Merck and the IRO shall hold an interim conference with the OIG to discuss the IRO's findings. The IRO shall present its findings, Merck shall present its management response, and the OIG shall review and consider the information provided by the IRO and Merck. Following consultations with Merck and the IRO, the OIG, in its discretion, shall determine whether an Additional Investigation shall be required. For any required Additional Investigation, the IRO shall review additional documentation and/or conduct additional interviews with appropriate personnel, as necessary, to identify the root cause of the net Error Rate.

Upon review of the discovery sample and any Additional Investigation, if warranted, for each universe of Transaction Types, the IRO shall report its findings to the OIG and Merck.

In its discretion, the OIG will determine whether the review of a statistically valid random sample of additional Transactions from the applicable universe shall be required and the size of that statistically valid random sample. The OIG shall base these determinations on discussions with the IRO and Merck, the results of the IRO's reviews of discovery samples, and the findings of any Additional Investigation that may have been deemed warranted.

The discovery samples (and additional samples that may be required) shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS" or through the use of another method of random sampling acceptable to the OIG.

D. BP Reported Prices Procedures

For each applicable Reporting Period, the IRO shall conduct BP Reported Prices Procedures to determine whether Merck calculated and reported BP in accordance with the requirements of the Medicaid Drug Rebate Program.

The BP Reported Prices Procedures shall consist of two parts:

1. Part One of BP Reported Prices Procedures

Merck shall provide the IRO with a list of all Merck Customers who purchased or contracted for Medicaid rebate eligible products during the selected quarter of the Reporting Period. The IRO shall randomly select a sample of 20 Merck Customers using the following methodology. The IRO shall aggregate the number of NDCs[1] for each Merck Customer and shall categorize each Merck Customer as "large" or "small" based upon the total volume of sales[2] of the contracted Medicaid rebate eligible NDCs to that Merck Customer in the selected quarter of the Reporting Period. The IRO shall randomly select 15 Merck Customers from the large Merck Customer category and 5 Merck Customers from the small Merck Customer category.

For each of the "large" and "small" Merck Customers identified by the IRO, the IRO's review shall cover the fifteen NDCs for which Merck paid the largest amount (i.e., total dollars) of Medicaid rebates during the Reporting Period and five randomly selected NDCs (collectively, the "Selected BP NDCs"). However for purposes of determining the Selected BP NDCs, if Merck paid less than $20,000 in Medicaid rebates during the Reporting Period for any randomly selected NDC, the IRO will replace that NDC with a randomly selected NDC for which Merck paid at least $20,000 in Medicaid rebates for the Reporting Period.

[1] For purposes of this Appendix A, "NDC" means a single dosage, form, and strength of a pharmaceutical product, without regard to package size (i.e., NDC 9).

[2] For purposes of this Section II.D, "volume of sales" means for the most recent quarter for which complete data is available: (i) net sales before government rebates; or (ii) for managed care and other similar entities, utilization.

For each Merck Customer selected, the IRO shall identify all contracts with Merck and all corresponding Medicaid rebate eligible NDCs for which the Merck Customer had a contract price with Merck. The IRO shall determine whether the contract price for each Selected BP NDC for products sold to the Merck Customer is accurately reflected in Merck's systems relevant for purposes of determining BP. The IRO shall determine whether the contract price is appropriately considered for purposes of determining BP in accordance with the requirements of the Medicaid Drug Rebate Program.

Merck shall also provide the IRO with information and documentation about all non-price-related arrangements or relationships initiated during the Review Period between Merck and the "large" and "small" Merck Customers identified by the IRO ("Other Arrangements"). These Other Arrangements could include, by way of example only, grants provided to the Merck Customer or data or service fee arrangements entered with the Merck Customer. The IRO shall review documentation and information about the Other Arrangements sufficient to identify the nature of the Other Arrangements, describe the terms of the Other Arrangements (including any amounts paid or other benefits conferred by Merck in connection with the Other Arrangements and the time periods of the arrangements), and identify any NDCs and/or Merck drugs that were the subject of the Other Arrangements.

2. Part Two of BP Reported Prices Procedures

Merck shall provide the IRO with the following information:

a) a listing of the ten Medicaid rebate eligible NDCs for which Merck paid the largest amount (i.e., total dollars) of Medicaid rebates during the Reporting Period; and

b) for each of the ten Medicaid rebate eligible NDCs selected, a listing of all unique prices paid to Merck for the product that were lower than the reported BP for the selected quarter.

For each unique price that was lower than the reported BP, the IRO shall review a minimum of five randomly selected contracted transactions associated with each of those unique lower prices (or, if

there are fewer than five such transactions, all such transactions) to determine whether each was properly excluded from the determination of BP for that Medicaid rebate eligible NDC in accordance with Medicaid Drug Rebate Program requirements.

3. Additional Investigations

If the BP Reported Prices Procedures reveal any prices that were not accurately reflected in Merck's systems and/or were not appropriately included in, or excluded from, Merck's BP determination in accordance with Medicaid Drug Rebate Program requirements, such prices shall be considered an error. The IRO shall conduct such Additional Investigation as may be necessary to determine the root cause of the error. For example, the IRO may need to review additional documentation, conduct additional interviews with appropriate personnel, and/or review additional contracts to identify the root cause of the error.

Upon completion of these reviews and any Additional Investigation(s) that may have been warranted, the IRO shall report its findings to the OIG.

In the event the IRO discovers more than one error for the quarter under review in Part One or Part Two of the BP Reported Prices Procedures, Merck and the IRO shall hold an interim conference with the OIG to discuss the IRO's findings. The IRO shall present its findings, Merck shall present its management response, and the OIG shall review and consider the information provided by the IRO and Merck. Following consultations with Merck and the IRO, the OIG, in its discretion, shall determine whether further review is warranted. Should the OIG determine that further review is warranted, the IRO shall randomly select and review a second sample as set forth below in this Section II.D.3, using the same seed number, and repeat Part One and/or Part Two of the BP Reported Prices Procedures (depending on whether one or both parts of the BP Reported Prices Procedures warranted an Additional Investigation).

Should the OIG determine that further review is warranted, the IRO shall:

a) If additional Part One review is required, randomly select five additional Merck Customers from the large Merck Customer category; and/or

b) If additional Part Two review is required, review the next five Medicaid rebate eligible NDCs for which Merck paid the largest amount (i.e., total dollars).

E. Medicaid Drug Rebate Review Report

1. General Requirements

The IRO shall prepare a report annually for each Medicaid Drug Rebate Review performed. The report shall contain the following general elements pertaining to both the AMP Reported Prices Procedures and the BP Reported Prices Procedures:

a) Medicaid Drug Rebate Review Objective(s) – a clear statement of the objective(s) intended to be achieved by each engagement;

b) Testing Protocol – a detailed narrative description of: (i) the procedures performed; (ii) the sampling units; and (iii) the universe from which the sample was selected; and

c) Sources of Data – a full description of documentation and/or other relevant information relied upon by the IRO when performing the reviews.

The IRO shall also include the following information in each Medicaid Drug Rebate Review Report:

2. AMP Reported Prices Procedures

a) A description of Merck's methodology for calculating AMP as reported for purposes of the Medicaid Drug Rebate Program, including its methodology for determining which classes of trade and types of transactions are included or excluded for purposes of calculating AMP;

b) For each universe of Transaction Types tested, the IRO shall state its findings and supporting evidence as to whether the Transaction

Types reviewed satisfied the corresponding criteria outlined above in Section II.C.1;

c) For each universe of Transaction Types tested, the IRO shall specify the net Error Rate discovered;

d) For each universe of Transaction Types for which the OIG determined that an Additional Investigation was required, the IRO shall explain its findings and describe supporting evidence;

e) For each universe of Transaction Types for which the IRO conducted a review on a second statistically valid sample as discussed in Section II.C.2, the IRO shall explain its findings and describe supporting evidence; and

f) The IRO shall report any recommendations for changes to Merck's policies, procedures, and/or methodologies to correct or address any weaknesses or deficiencies discovered during the AMP Reported Prices Procedures.

3. BP Reported Prices Procedures – Part One

a) a description/identification of the following: (i) the 20 Merck Customers selected under Part One; (ii) the number of contracts associated with each Merck Customer; (iii) the Selected BP NDCs tested; (iv) the contract prices for each NDC tested; and (v) a description of any supporting documentation reviewed;

b) a description of the IRO's stratification system for identifying the "large" and "small" Customers and documentation supporting the random selection of the Customers;

c) for each selected Merck Customer, a description of the steps taken to determine whether the contract price(s) for each Selected BP NDC was (were) accurately reflected in Merck's systems;

d) for each selected Merck Customer, the IRO's determination regarding whether each Selected BP NDC contract price was accurately reflected in Merck's contracting systems. If the correct price was not reflected in the systems, the IRO should identify the correct price;

e) a detailed description of any Additional Investigation or further review undertaken with regard to any Selected BP NDC price not accurately reflected in Merck's systems and the results of any Additional Investigation or further review undertaken with respect to any such price;

f) for each selected Merck Customer, a description of the steps taken to determine whether each contract price(s) was (were) appropriately considered in Merck's determination of the BPs for the Select BP NDCs in accordance with Medicaid Drug Rebate Program requirements;

g) for each selected Merck Customer: (i) a list of any price not properly included in, or excluded from, Merck's BP determination for the applicable quarter; (ii) a description of any adjustments to BP reported to CMS; and (iii) a description of any additional follow-up action taken by Merck;

h) a detailed description of any Additional Investigation or further review undertaken with regard to any price not appropriately included in, or excluded from, Merck's BP determination for the selected quarter, and the results of any Additional Investigation or further review undertaken with respect to any such price;

i) for each selected Merck Customer: (i) a description of the nature of all Other Arrangements entered between Merck and the Merck Customer; (ii) a description of the terms of all Other Arrangements (including any amounts paid or other benefits conferred by Merck in connection with the Other Arrangements and the time periods of the arrangements); (iii) an identification of any NDCs and/or Merck drugs that were the subject of the Other Arrangements; and (iv) a description of the documentation or information reviewed with regard to all Other Arrangements; and

j) the IRO's recommendations for changes in Merck's policies, procedures, and/or methodologies to correct or address any weaknesses or deficiencies discovered during the review.

4. BP Reported Prices Procedures – Part Two

a) a list of: (i) the ten Medicaid rebate eligible NDCs with the highest rebates paid by Merck during the Reporting Period; (ii) the BP

reported by Merck to CMS for the Medicaid Drug Rebate Program for each of the ten NDCs under review; and (iii) a description of the underlying documentation supporting the random selection of the five contacted transactions associated with each unique price lower than the reported BPs;

b) a description of the steps and the supporting documentation reviewed to assess the unique lower prices for each of the selected NDCs which were below the BPs reported by Merck to CMS. If more than five contracted transactions are associated with any of the unique lower prices, the IRO shall also identify how many such transactions exist for each unique lower price;

c) a list of any prices not properly excluded from Merck's BP determination for any of the ten NDCs reviewed; a description of any adjustments to BP reported to CMS; and a description of any additional follow-up action taken by Merck for any of the ten NDCs reviewed;

d) a detailed description of any Additional Investigation or further review undertaken with regard to any prices that were not properly excluded from Merck's BP determination for any of the ten NDCs reviewed and the results of any such Additional Investigation or further review; and

e) the IRO's recommendations for changes in Merck's policies, procedures, and/or methodologies to correct or address any weaknesses or deficiencies discovered during the review.

APPENDIX B TO CIA FOR MERCK & CO., INC.

PROMOTIONAL AND PRODUCT SERVICES REVIEW

I. Promotional and Product Services Review, General Description

As specified more fully below, Merck shall retain an Independent Review Organization (IRO) to perform reviews to assist Merck in assessing and evaluating its systems, processes, policies, procedures, and practices related to Merck's Promotional Functions, Product Related Functions, and Government Payor Related Functions (IRO Review). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Merck may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Merck's systems, processes, policies, and procedures relating to Promotional Functions, Product Related Functions, and Government Payor Related Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Merck materially changes its systems, processes, policies, and procedures relating to Promotional Functions, Product Related Functions, and Government Payor Related Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of Merck's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional Functions, Product Related Functions, and Government Payor Related Functions. Where practical, Merck personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Merck in accordance with the preceding sentence.

Specifically, the IRO shall review Merck's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Merck's systems, policies, processes, and procedures applicable to the manner in which Merck representatives (including sales representatives, marketing personnel, and/or GMA department personnel) handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses Government Reimbursed Products) and the dissemination of materials relating to off-label uses of Government Reimbursed Products. This review includes:

a) the manner in which Merck sales representatives and marketing personnel handle requests for information about off-label uses of Government Reimbursed Products (*e.g.*, by referring all such requests to GMA personnel at Merck);
b) the manner in which GMA personnel, including those at Merck's headquarters, handle and respond to requests for information about off-label uses of Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
c) the form and content of information and materials related to Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions (HCIs) by Merck;
d) Merck's systems, processes, and procedures (including the Inquiries Database) to track requests for information about off-label uses of Government Reimbursed Products and responses to those requests;
e) the manner in which Merck collects and supports information reported in any systems used to track and respond to requests for Government Reimbursed Product information, including its Inquiries Database;
f) the processes and procedures by which Merck identifies situations in which it appears that off-label or other improper promotion may have occurred; and
g) Merck's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

2) Merck's systems, policies, processes, and procedures applicable to the manner and circumstances under which its GMA personnel (including any medical science specialists or analogous personnel) participate in

meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of the medical personnel at such meetings or events;

3) Merck's systems, policies, processes, and procedures relating to Merck's internal review and approval of information and materials related to Government Reimbursed Products disseminated to HCPs or HCIs by Merck;

4) Merck's systems, polices, processes and procedures relating to incentive compensation for Relevant Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Merck establishes different methods of compensation for different products, the IRO shall review each type of compensation arrangement separately;

5) Merck's systems, processes, policies, and procedures relating to the development and review of call plans for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties or types of clinical practices are included in, or excluded from, the call plans based on expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

6) Merck's systems, processes, policies, and procedures relating to sample distribution. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Merck (including, separately, from Merck sales representatives and other Merck personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by Merck through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

7) Merck's systems (including any centralized electronic system to manage speaker program logistics), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

8) Merck's systems, processes, policies, and procedures relating to non-speaker related consultant or other fee-for-service arrangements regarding a Covered Function entered into with HCPs or HCIs (including, but not limited to, presentation, consultant task force meetings, advisory boards, preceptorships, mentorships (if any), and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements and arrangements;

9) Merck's systems, processes, policies, and procedures relating to the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the Product ("Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information, (e.g., any changes based on Merck's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia). The review shall also assess Merck's processes relating to its annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by the company to any Compendia;

10) Merck's systems, processes, policies, and procedures relating to investigator-initiated studies (IISs) conducted by U.S.-licensed HCPs or HCIs including the decision to provide financial or other support for IISs; the manner in which support is provided for the IISs; and support for publication of the information about the IISs, including publication of information about the trial outcomes and results and the uses made of publications relating to IISs;

11) Merck's systems, processes, policies and procedures relating to authorship of any articles or other publications about Government Reimbursed Products or therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all relationships between the author and Merck, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

12) Merck's systems, policies, processes, and procedures applicable to the manner in which Merck representatives provide information about Government Reimbursed Products (including information about both FDA-approved and non-FDA-approved (*i.e.*, off-label) uses of Government Reimbursed Products) to state Medicaid payors, pharmacy benefit managers

(PBMs), or other individuals or entities under contract with or acting on behalf of State Medicaid payors (collectively, "Government payors");

13) Merck's systems, policies, processes, and procedures applicable to the manner and circumstances under which its Merck personnel (including sales representatives, medical science specialists, or analogous personnel) participate in meetings with Government payors regarding Government Reimbursed Products and the role of the Merck personnel at such meetings; and

14) the form and content of information and materials disseminated by Merck to Government payors and Merck's systems, policies, processes, and procedures relating to Merck's internal review and approval of information and materials related to Government Reimbursed Products disseminated to Government payors by Merck.

B. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

1) a description of the documentation (including policies) reviewed and any personnel interviewed;

2) a detailed description of Merck's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-14 above, including a general description of Merck's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-14 above are made known or disseminated within Merck;

4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Database);

5) findings and supporting rationale regarding any weaknesses in Merck's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. IRO Transaction Review

As described more fully below in Sections III.A-D, the Transactions Review shall include: (1) a review of Merck's call plans and Merck's call plan review process; (2) a review of Sampling Events as defined below in Section III.B; (3) a review of records relating to a sample of the Payments that are reported by Merck pursuant to Section III.M of the CIA; and (4) a review of up to three additional items identified by the OIG in accordance with Section III.D.1.b of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Promotional and Product Services Transactions Review Reports.

A. IRO Review of Merck's Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of Merck's review of its call plans for Government Reimbursed Products as set forth in Section III.B.3.i of the CIA. Merck shall provide the IRO with: i) a list of Government Reimbursed Products promoted by Merck during the Reporting Period; ii) information about the FDA-approved uses for each Merck Government Reimbursed Product; and iii) the call plans for each Government Reimbursed Product. Merck shall also provide the IRO with information about the reviews of call plans that Merck conducted during the Reporting Period and any modifications to the call plans made as a result of Merck's reviews.

For each call plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by Merck in conducting its review and/or modifying the call plan. The IRO shall seek to determine whether Merck followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs on a particular call plan are inconsistent with Merck's criteria relating to the call plan and/or Merck's Policies and Procedures. The IRO shall also note any instances in which it appears that Merck failed to follow its criteria or Policies and Procedures.

B. IRO Review of the Distribution of Samples of Merck Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. Merck shall provide the IRO

with: i) a list of Government Reimbursed Products for which Merck distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each Merck Government Reimbursed Product for which Merck distributed samples during the Reporting Period; and iii) information about Merck's policies and procedures relating to the distribution of samples of each type of Government Reimbursed Product, including Merck's Sample Distribution Plan showing which types of samples may be distributed by sales representatives to HCPs and HCIs of particular medical specialties or types of clinical practices. Merck shall also provide the IRO with information about the reviews of Sample Distribution Plans that Merck conducted during the Reporting Period as set forth in Section III.B.3.j of the CIA and any modifications to the distribution plans made as a result of Merck's reviews.

For each product for which Merck distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which Merck provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the Merck product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual Merck sales representative or department (e.g., GMA) provided the sample to the HCP or HCI; and 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter or call to GMA department).

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the product approved by the FDA and whether the sample was distributed by a Merck representative in a manner consistent with Merck's sample distribution policy for the Government Reimbursed Product(s) provided during the Sampling Event. To the extent that the review of Sampling Events identifies a sample was provided to an HCP or HCI by a Merck representative other than a sales representative, the IRO shall contact the HCP or HCI using a letter agreed to by the IRO and Merck. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a Merck sales representative, conversation with a representative of Merck's GMA department, independent research or knowledge of the HCP or HCI, etc.).

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the product

approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the FDA. For each such situation, the IRO shall note the process followed by Merck in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that Merck failed to follow its Sample Distribution Plan for the product(s) provided during the Sampling Event.

C. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

For purposes of the IRO review as set forth in this Section III.C, each annual listing of physicians and Related Entities who received Payments shall be referred to as the "Physician Payment Listing" or "Listing." For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state of the physician's practice or the Related Entity; and (iv) the aggregate value of the Payment(s) in the preceding year(s).

For purposes of this IRO review, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for a sampled physician and/or Related Entity. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in Listing

identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;

b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Merck's policies;

c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payments(s) reflected in the Control Documents; and

d) Whether the Control Documents reflect that Merck's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Merck's policies).

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:

   i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
   ii. the IRO cannot confirm that Merck otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or

b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Merck's policies

and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Merck has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Merck otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

D. IRO Review of Additional Items

As set forth in Section III.D.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). No later than 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Merck of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Merck shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Merck's systems, processes, policies, and procedures based on its review of each Additional Item).

Merck may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Merck's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Merck's planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Merck's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Merck's request to

permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Merck shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of Merck's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Merck in its internal audits.

E. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1) General Elements to Be Included in Report

a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Transaction Review Report:

(Relating to the Call Plan Reviews)

a) a list of the Government Reimbursed Products promoted by Merck during the Reporting Period and a summary of the FDA-approved uses for such Government Reimbursed Products;

b) for each Merck Government Reimbursed Product which was promoted during the Reporting Period: i) a description of the criteria

used by Merck in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) a description of the review conducted by Merck of the call plans and an indication of whether Merck reviewed the call plans as required by Section III.B.3.i of the CIA; iii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with Merck's criteria relating to the call plan and/or Merck's Policies and Procedures; and iv) a description of all instances in which it appears that Merck failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;

c) the findings and supporting rationale regarding any weaknesses in Merck's systems, processes, policies, procedures, and practices relating to Merck's call plans or the review of the call plans, if any;

d) recommendations, if any, for changes in Merck's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans or the review of the call plans;

(Relating to the Sampling Event Reviews)

e) for each Merck Government Reimbursed Product for which samples were provided during the Reporting Period: i) a description of Sample Distribution Plan (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by Merck in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that Merck failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event;

f) the findings and supporting rationale regarding any weaknesses in Merck's systems, processes, policies, procedures, and practices

relating to Merck's distribution of samples of Merck Government Reimbursed Products, if any;

g) recommendations, if any, for changes in Merck's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

h) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;

i) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Merck policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Merck's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) disciplinary action was undertaken in those instances in which Merck policies were not followed;

j) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;

k) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

l) for each Additional Item reviewed, a description of the review conducted;

m) for each Additional Item reviewed, the IRO's findings based on its review;

n) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Merck's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

o) for each Additional Item reviewed, recommendations, if any, for changes in Merck's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

APPENDIX C TO CIA FOR MERCK & CO., INC.

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement.

Merck shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the information set forth in Sections V.A.6 of the CIA, OIG will notify Merck if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Merck may continue to engage the IRO.

If Merck engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Merck shall submit the information identified in Section V.A.6 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Merck if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Merck may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Medicaid Drug Rebate Reviews and the Promotional and Product Services Reviews who have expertise in all applicable Federal health care program and FDA requirements relating to the Covered Functions (as defined in Section II.C.8 of the CIA) and in the general requirements of the Federal health care program(s) under which Merck's products are reimbursed;

2. assign individuals to the Medicaid Drug Rebate Review and the Promotional and Product Services Review who are knowledgeable about appropriate techniques required for the Reviews, including assigning individuals who are knowledgeable about appropriate statistical sampling techniques to design and select samples for the Transaction Reviews; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Medicaid Drug Rebate Review and Promotional and Product Services Review in accordance with the specific requirements of the CIA, including Appendices A-B, as applicable;

2. follow all applicable Federal health care program requirements in making assessments in each Medicaid Drug Rebate Review and Promotional and Product Services Review;

3. if in doubt of the application of a particular Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendices A and B.

D. IRO Independence and Objectivity.

The IRO must perform each Medicaid Drug Rebate Review and Promotional and Product Services Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Merck.

E. IRO Removal/Termination.

1. *Provider*. If Merck terminates its IRO during the course of the engagement, Merck must submit a notice explaining its reasons to OIG no later than 30 days after termination. Merck must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

2. *OIG Removal of IRO*. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Merck to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Merck to engage a new IRO, OIG shall notify Merck of its intent to do so and provide a written explanation of why OIG believes such a step is necessary.

To resolve any concerns raised by OIG, Merck may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence, or performance of its responsibilities and to present additional information regarding these matters. Merck shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Merck prior to requiring Merck to terminate the IRO. However, the final determination as to whether or not to require Merck to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX D TO CIA FOR MERCK & CO., INC.

Certification

In accordance with the Corporate Integrity Agreement (CIA) entered between Merck and Co., Inc. (Merck) and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information, and belief:

1) Merck has in place policies and procedures describing in all material respects its methods for collecting, calculating, verifying, and reporting the data and information reported to the Centers for Medicare and Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate Program (Medicaid Rebate Policies and Procedures);

2) the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with Merck's obligations under the Medicaid Drug Rebate Program;

3) Merck's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Average Manufacturer Price (AMP) and Best Price (BP) for Merck's products for each of the below-listed four quarters: [specifically identify the applicable quarters]; and

I hereby certify that the AMPs and BPs reported to CMS in the above-listed quarters were calculated accurately and all information and statements made in connection with the submission of AMPs and BPs and in this Certification are true, complete, and current and are made in good faith.

_____

Signature

_____

Name of CEO, CFO, or other appropriate individual consistent with 42 C.F.R. § 447.510(e)

_____

Date